

will be better served if we don't give them," said Dr. Richard Rosenfeld, a member of the committee reviewing the guidelines.

"We should save the power of antibiotics for people with real significant illnesses where 80 percent don't get better in a day or two and can actually die," he said.

As the guidelines are currently proposed, doctors would prescribe antibiotics only for children with serious middle ear infections, known as acute otitis media. Symptoms include a minimum fever of 102.6 degrees or severe ear pain. Milder cases would simply be observed.

Between 5 million and 6 million children under age 5 suffer ear infections each year. Antibiotics are prescribed in many of those visits, said Rosenfeld, also director of pediatric otolaryngology at Long Island College Hospital in Brooklyn, N.Y.

About 10 million prescriptions each year are written for ear infections in children of all ages.

Health officials believe the new guidelines won't cause any extra office visits for parents, although they may be asked to update pediatricians with their child's condition by phone, said Dr. Allan Lieberthal, co-chairman of the medical groups' committee reviewing the guidelines change.

A specific definition for doctors of what constitutes a serious ear infection also is expected to reduce antibiotic overuse.

"Antibiotics only will be considered if it's truly acute otitis media and not every abnormal-appearing ear," Lieberthal said.

Medical studies have found the antibiotics do very little for a child's ear infection pain. Common painkillers such as acetaminophen or ibuprofen are effective for that, said Lieberthal, also a pediatrician for Kaiser Permanente in Panorama City, Calif.

"Since the discovery of penicillin, when there is a bacterial infection, antibiotics are given," Lieberthal said. "Because of the increasing resistance of common bacteria to antibiotics, the importance of limiting their use is essential."

On the Net:

CDC antimicrobial resistance info:

www.cdc.gov/drugresistance/healthcare

American Academy of Pediatrics info: www.aap.org

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Practice Guideline

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Managing Otitis Media With Effusion in Young Children

AMERICAN ACADEMY OF PEDIATRICS

The Otitis Media Guideline Panel

• **ABSTRACT.** This reference guide contains highlights from the *Clinical Practice Guideline, Otitis Media with Effusion in Young Children*. The Otitis Media Guideline Panel, a private-sector panel of health care providers, developed the Guideline after comprehensively analyzing the research literature and current scientific knowledge of the development, diagnosis, and treatment of otitis media with effusion in young children.

• Specific recommendations are given for the management of otitis media with effusion in young children age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits. The natural history of otitis media with effusion, the functional impairments that may result from otitis media with effusion, and the difficulty of measuring the effects of medical and surgical interventions on long-term outcomes are included. The medical interventions studied involve antibiotic, steroid, and antihistamine/decongestant therapies. The surgical interventions studied involve myringotomy with insertion of tympanostomy tubes, adenoidectomy, and tonsillectomy. Short-term outcomes addressed are resolution of effusion and restoration of hearing.

ABBREVIATIONS. OME, otitis media with effusion; AHCPR, Agency for Health Care Policy and Research.

PURPOSE AND SCOPE

Otitis media (inflammation of the middle ear) is the most frequent primary diagnosis at visits to US physician offices by children younger than 15 years. Otitis media particularly affects infants and preschoolers: almost all children experience one or more episodes of otitis media before age 6.

The American Academy of Pediatrics, the American Academy of Family Physicians, and the American Academy of Otolaryngology--Head and Neck Surgery, with the review and approval of the Agency for Health Care Policy and Research of the US Department of Health and Human Services, convened a panel of experts to develop a guideline on otitis media for providers and consumers of health care for young children. Providers include primary care and specialist physicians, professional nurses and nurse practitioners, physician assistants, audiologists, speech-language pathologists, and child development specialists. Because the term otitis media encompasses a range of diseases, from acute to chronic and with or without symptoms, the Otitis Media Guideline Panel narrowed the topic. Two types of otitis media often encountered by clinicians were considered:

- *Acute otitis media*--fluid in the middle ear accompanied by signs or symptoms of ear infection (bulging eardrum usually accompanied by pain; or perforated eardrum, often with drainage of purulent

material).

- *Otitis media with effusion*--fluid in the middle ear without signs or symptoms of ear infection.

The *Clinical Practice Guideline, Otitis Media with Effusion in Young Children*, and this reference guide, discuss only otitis media with effusion. Furthermore, the *Guideline* and this document narrow their discussion of the identification and management of otitis media with effusion to a very specific "target patient":

- A child age 1 through 3 years;
- with no craniofacial or neurologic abnormalities or sensory deficits;
- and who is healthy except for otitis media with effusion.

When the scientific evidence for management permitted, Guideline recommendations were broadened to include older children.

HIGHLIGHTS OF PATIENT MANAGEMENT

Congenital or early onset hearing impairment is widely accepted as a risk factor for impaired speech and language development. In general, the earlier the hearing problem begins and the more severe it is, the worse its effects on speech and language development. Because otitis media with effusion is often associated with a mild to moderate hearing loss, most clinicians have been eager to treat the condition to restore hearing to normal and thus prevent any long-term problems.

Studies of the effects of otitis media with effusion on hearing have varied in design and have examined several aspects of hearing and communication skills. Because of these differences, the results cannot be combined to provide a clear picture of the relationship between otitis media with effusion and hearing. Also, it is uncertain whether changes in hearing due to middle ear fluid have any long-term effects on development. Evidence of dysfunctions mediated by otitis media with effusion that have persisted into later childhood, despite resolution of the middle ear fluid and a return to normal hearing, would provide a compelling argument for early, decisive intervention. There is, however, no consistent, reliable evidence that otitis media with effusion has such long-term effects on language or learning.

The following recommendations for managing otitis media with effusion are tempered by the failure to find rigorous, methodologically sound research to support the theory that untreated otitis media with effusion results in speech/language delays or deficits.

Recommendations and options were developed for the diagnosis and management of otitis media with effusion in otherwise healthy young children. The following steps parallel the management algorithm provided at the end of this document.

Diagnosis and Hearing Evaluation

1) Suspect otitis media with effusion in young children. Most children have at least one episode of otitis media with effusion before entering school. Otitis media with effusion may be identified following an acute episode of otitis media, or it may be an incidental finding. Symptoms may include discomfort or

behavior changes.

2) Use pneumatic otoscopy to assess middle ear status. Pneumatic otoscopy is recommended for assessment of the middle ear because it combines visualization of the tympanic membrane (otoscopy) with a test of membrane mobility (pneumatic otoscopy). When pneumatic otoscopy is performed by an experienced examiner, the accuracy for diagnosis of otitis media with effusion may be between 70% and 79%.

3) Tympanometry may be performed to confirm suspected otitis media with effusion. Tympanometry provides an indirect measure of tympanic membrane compliance and an estimate of middle ear air pressure. The positive predictive value of an abnormal (type B, flat) tympanogram is between 49% and 99%; that is, as few as half of ears with abnormal tympanograms may have otitis media with effusion. The negative predictive value of this test is better--the majority of middle ears with normal tympanograms will in fact be normal. Because the strengths of tympanometry (it provides a quantitative measure of tympanic membrane mobility) and pneumatic otoscopy (many abnormalities of the eardrum and ear canal that can skew the results of tympanometry are visualized) offset the weaknesses of each, using the two tests together improves the accuracy of diagnosis.

- *Acoustic reflectometry* has not been studied well enough for a recommendation to be made for or against its use to diagnose otitis media with effusion.

- *Tuning fork tests:* No recommendation is made regarding the use of tuning fork tests to screen for or diagnose otitis media with effusion, except to note that they are inappropriate in the youngest children.

4) A child who has had fluid in both middle ears for a total of 3 months should undergo hearing evaluation. Before 3 months of effusion, hearing evaluation is an option. A change in hearing threshold is both a clinical outcome and a possible indicator of the presence of otitis media with effusion. Methods used to determine a child's hearing acuity will vary depending on the resources available and the child's willingness and ability to participate in testing. Optimally, air- and bone-conduction thresholds can be established for 500, 1000, 2000, and 4000 Hz, and an air-conduction pure tone average can be calculated. This result should be verified by obtaining a measure of speech sensitivity. Determinations of speech reception threshold or speech awareness threshold alone may be used if the child cannot cooperate for pure tone testing. If none of the test techniques is available or tolerated by the child, the examiner should use his/her best judgment as to adequacy of hearing. In these cases, the health care provider should be aware of whether the child is achieving the appropriate developmental milestones for verbal communication.

Although hearing evaluation may be difficult to perform in young children, evaluation is recommended after otitis media with effusion has been present bilaterally for 3 months, because of the strong belief that surgery is not indicated unless otitis media with effusion is causing hearing impairment (defined as equal to or worse than 20 decibels hearing threshold level in the better-hearing ear).

Natural History

Longitudinal studies of otitis media with effusion show spontaneous resolution of the condition in more than half of children within 3 months from development of the effusion. After 3 months the rate of spontaneous resolution remains constant, so that only a small percentage of children experience otitis media with effusion lasting a year or longer. In most children, episodes of otitis media with effusion do not persist beyond early childhood. The likelihood that middle ear fluid will resolve by itself underlies the recommendations made for management of otitis media with effusion.

Environmental Risk Factors

Scientific evidence showed that the following environmental factors may increase potential risks of getting acute otitis media or otitis media with effusion:

- Bottle-feeding rather than breast-feeding infants.
- Passive smoking.
- Group child-care facility attendance.

Because the target child for Guideline recommendations is beyond the age when the choice of breast-feeding versus bottle-feeding is an issue, this risk factor was not considered at length.

Passive smoking (exposure to another's tobacco smoke) is associated with higher risk of otitis media with effusion. Although there is no proof that stopping passive smoking will help prevent middle ear fluid, there are many health reasons for not exposing persons of any age to tobacco smoke. Therefore, clinicians should advise parents of the benefits of decreasing children's exposure to tobacco smoke.

Studies of otitis media with effusion in children cared for at home compared to those in group child-care facilities found that children in group child-care facilities have a slightly higher relative risk (less than 2.0) of getting otitis media with effusion. Research did not show whether removing the child from the group child-care facility helped prevent otitis media with effusion.

Therapeutic Interventions

5) Observation OR antibiotic therapy are treatment options for children with effusion that has been present less than 4 to 6 months and at any time in children without a 20-decibel hearing threshold level or worse in the better-hearing ear. Most cases of otitis media with effusion resolve spontaneously. Meta-analysis of controlled studies showed a 14% increase in the resolution rate when antibiotics were given. Length of treatment in these studies was typically 10 days.

The most common adverse effects of antibiotic therapy are gastrointestinal. Dermatologic reactions may occur in 3% to 5% of cases; severe anaphylactic reactions are much rarer; severe hematologic, cardiovascular, central nervous system, endocrine, renal, hepatic, and respiratory adverse effects are rarer still. The potential for the development of microbial resistance is always present with antibiotics.

6) For the child who has had bilateral effusion for a total of 3 months and who has a bilateral hearing deficiency (defined as a 20-decibel hearing threshold level or worse in the better-hearing ear), bilateral myringotomy with tube insertion becomes an additional treatment option. Placement of tympanostomy tubes is recommended after a total of 4 to 6 months of bilateral effusion with a bilateral hearing deficit. The principal benefits of myringotomy with insertion of tympanostomy tubes are the restoration of hearing to the pre-effusion threshold and clearance of the fluid and possible feeling of pressure. While patent and in place, tubes may prevent further accumulation of fluid in the middle ear. Although there is insufficient evidence to prove that there are long-term deleterious effects of otitis media with effusion, concern about the possibility of such effects led the panel to recommend surgery, based on their expert opinion. Tubes are available in a myriad of designs, most constructed from plastic and/or metal. Data comparing outcomes with tubes of various designs are sparse, and so there were assumed to be no notable differences between available tympanostomy tubes.

Insertion of tympanostomy tubes is performed under general anesthesia in young children. Calculation of the risks for two specific complications of myringotomy with tympanostomy tube insertion showed that tympanosclerosis might occur after this procedure in 51%, and postoperative otorrhea in 13%, of children.

A number of treatments are not recommended for treatment of otitis media with effusion in the otherwise healthy child age 1 through 3 years.

- *Steroid medications* are not recommended to treat otitis media with effusion in a child of any age because of limited scientific evidence that this treatment is effective and the opinion of many experts that the possible adverse effects (agitation, behavior change, and more serious problems such as disseminated varicella in children exposed to this virus within the month before therapy) outweighed possible benefits.
- *Antihistamine/decongestant therapy* is not recommended for treatment of otitis media with effusion in a child of any age, because review of the literature showed that these agents are not effective for this condition, either separately or together.
- *Adenoidectomy* is not an appropriate treatment for uncomplicated middle ear effusion in the child younger than age 4 years when adenoid pathology is not present (based on the lack of scientific evidence). Potential harms for children of all ages include the risks of general anesthesia and the possibility of excessive postoperative bleeding.
- *Tonsillectomy, either alone or with adenoidectomy*, has not been found effective for treatment of otitis media with effusion.
- *The association between allergy and otitis media with effusion* was not clear from available evidence. Thus, although close anatomic relationships between the nasopharynx, eustachian tube, and middle ear have led many experts to suggest a role for allergy management in treating otitis media with effusion, no recommendation was made for or against such treatment.
- *Evidence regarding other therapies for the treatment of otitis media with effusion* was sought, but no reports of chiropractic, holistic, naturopathic, traditional/indigenous, homeopathic, or other treatments contained information obtained in randomized controlled studies. Therefore, no recommendation was made regarding such other therapies for the treatment of otitis media with effusion in children.

Treatment Outcomes

The [Table](#) summarizes the benefits and harms identified for management interventions in the target child with otitis media with effusion.

ALGORITHM

The notes below are an integral part of the algorithm that follows.

(A) Otitis media with effusion (OME) is defined as fluid in the middle ear without signs or symptoms of infection; OME is not to be confused with acute otitis media (inflammation of the middle ear with signs of infection). The Guideline and this algorithm apply only to the child with otitis media with effusion. This algorithm assumes followup intervals of 6 weeks.

- (B) The algorithm applies only to a child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits (except as noted) who is healthy except for otitis media with effusion. The Guideline recommendations and algorithm do not apply if the child has any craniofacial or neurologic abnormality (for example, cleft palate or mental retardation) or sensory deficit (for example, decreased visual acuity or pre-existing hearing deficit).
- (C) The Panel found some evidence that pneumatic otoscopy is more accurate than otoscopy performed without the pneumatic test of eardrum mobility.
- (D) Tympanometry may be used as confirmation of pneumatic otoscopy in the diagnosis of OME. Hearing evaluation is recommended for the otherwise healthy child who has had bilateral OME for 3 months; before 3 months, hearing evaluation is a clinical option.
- (E) In most cases, OME resolves spontaneously within 3 months.
- (F) The antibiotic drugs studied for treatment of OME were amoxicillin, amoxicillin-clavulanate potassium, cefaclor, erythromycin, erythromycin-sulfisoxazole, sulfisoxazole, and trimethoprim-sulfamethoxazole.
- (G) Exposure to cigarette smoke (passive smoking) has been shown to increase the risk of OME. For bottle-feeding versus breast-feeding and for child-care facility placement, associations were found with OME, but evidence available to the Panel did not show decreased incidence of OME with breast-feeding or with removal from child-care facilities.
- (H) The recommendation against tonsillectomy is based on the lack of added benefit from tonsillectomy when combined with adenoidectomy to treat otitis media with effusion in older children. Tonsillectomy and adenoidectomy may be appropriate for reasons other than otitis media with effusion.
- (I) The Panel found evidence that decongestants and/or antihistamines are ineffective treatments for otitis media with effusion.
- (J) Meta-analysis failed to show a significant benefit for steroid medications without antibiotic medications in treating otitis media with effusion in children.

Click for [algorithm](#)

This guide was developed by the American Academy of Pediatrics under contract with the Agency for Health Care Policy and Research (AHCPR) and in consortium with the American Academy of Family Physicians and the American Academy of Otolaryngology-Head and Neck Surgery (the "Consortium"). With AHCPR approval, the Consortium convened an interdisciplinary, non-Federal panel comprising health care professionals and a consumer representative. Panel members were:

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For a description of the guideline development process and information about the sponsoring agency (AHCPR), see the *Clinical Practice Guideline, Otitis Media with Effusion in Young Children* (AHCPR Publication 94-0622). To receive copies of the *Clinical Practice Guideline*, as well as this guide (AHCPR Publication 94-0623) and *Middle Ear Fluid in Children: Parent Guide* (AHCPR Publication 94-0624), call toll free (800-358-9295) or write the AHCPR Publications Clearinghouse, PO Box 8547, Silver Spring, MD 20907.

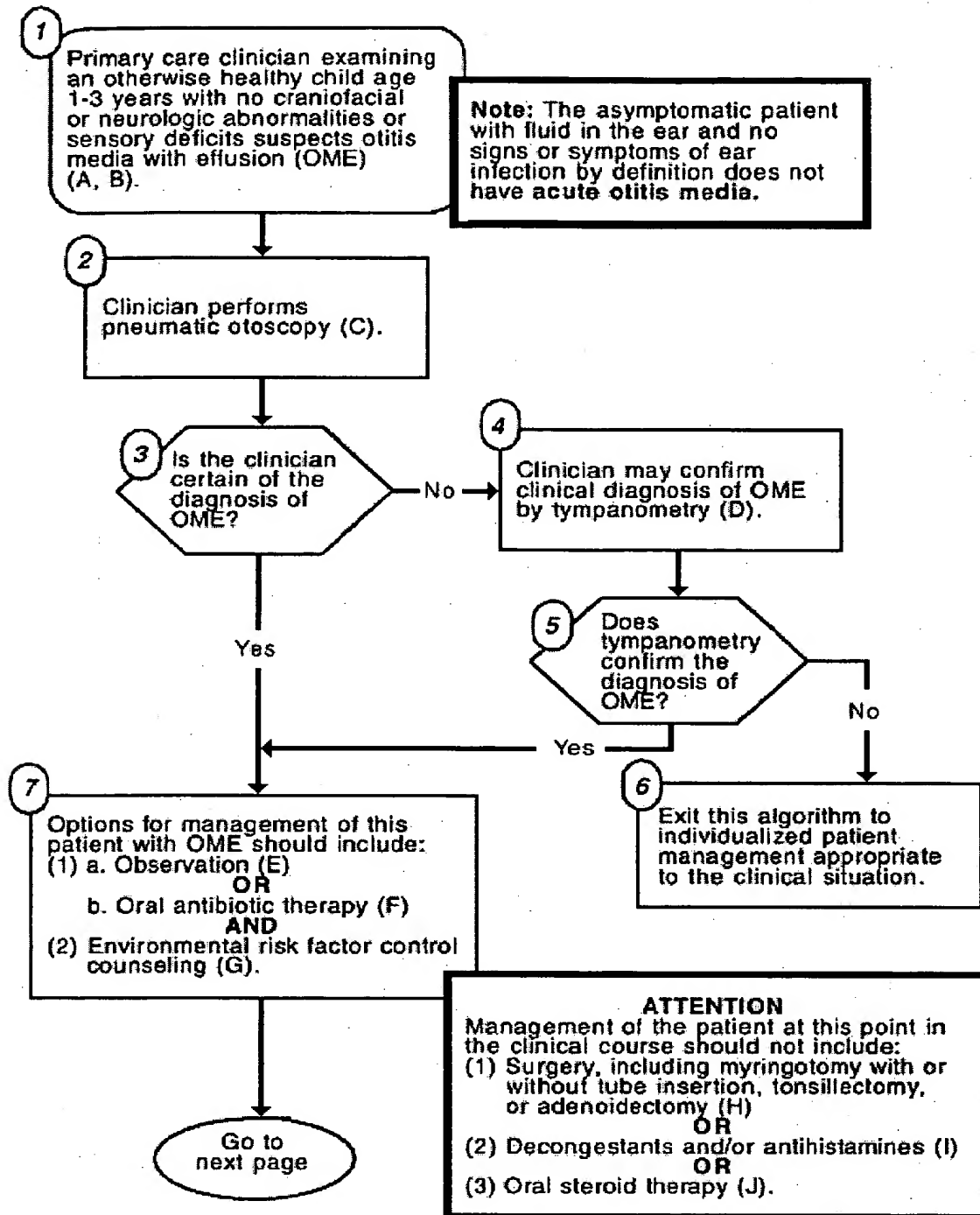
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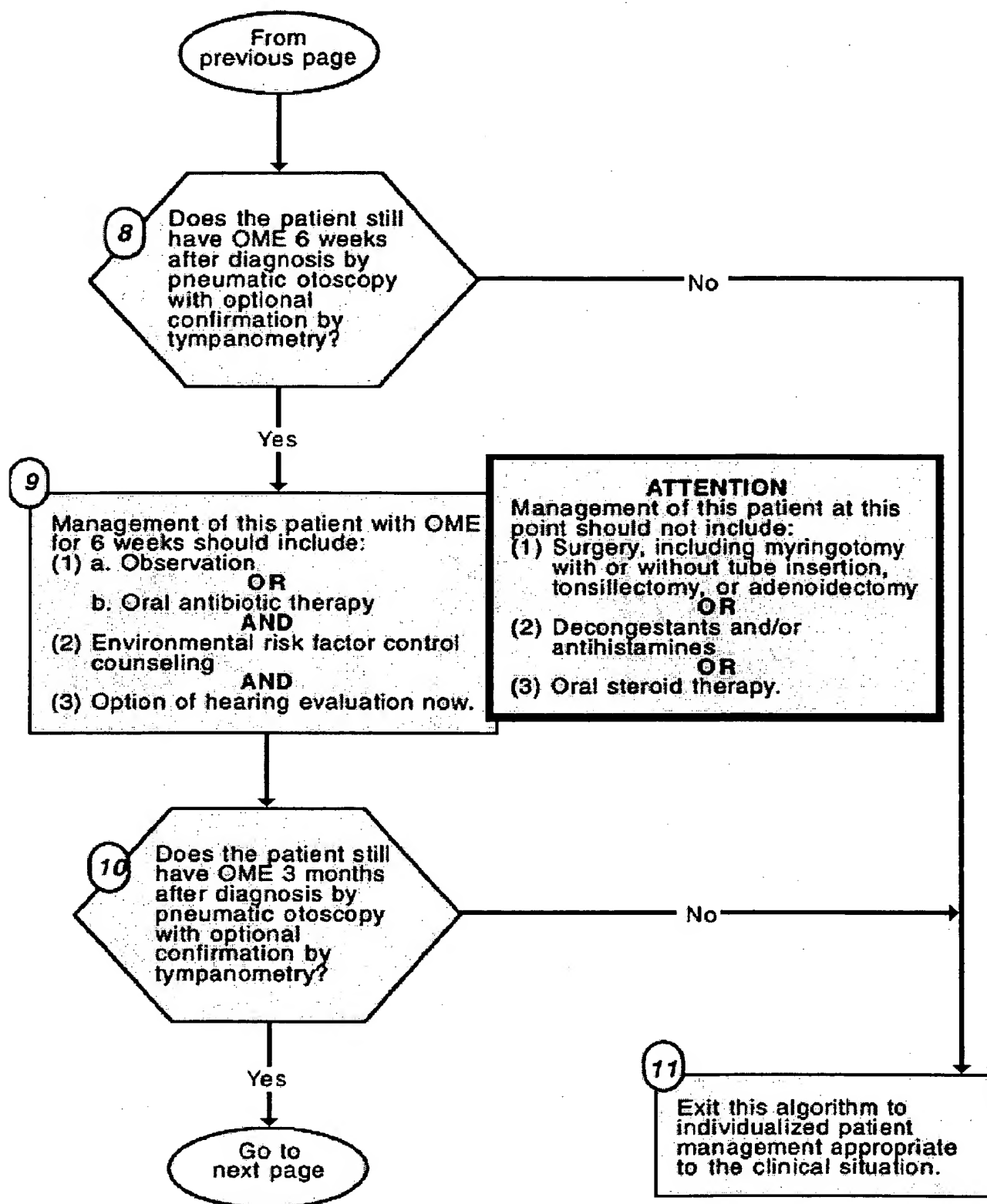
This reference guide presents summary points from the *Clinical Practice Guideline*. The *Clinical Practice Guideline* provides more detailed analysis and discussion of the available research, health care decisionmaking, critical evaluation of the assumptions and knowledge of the field, considerations for patients with special needs, and references. Decisions to adopt any particular recommendation from any publication must be made by practitioners in light of available resources and circumstances presented by individual patients.

The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed. Variations, taking into account individual circumstances, may be appropriate.

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ALGORITHM for managing otitis media with effusion in an otherwise healthy child age 1 to 3 years:





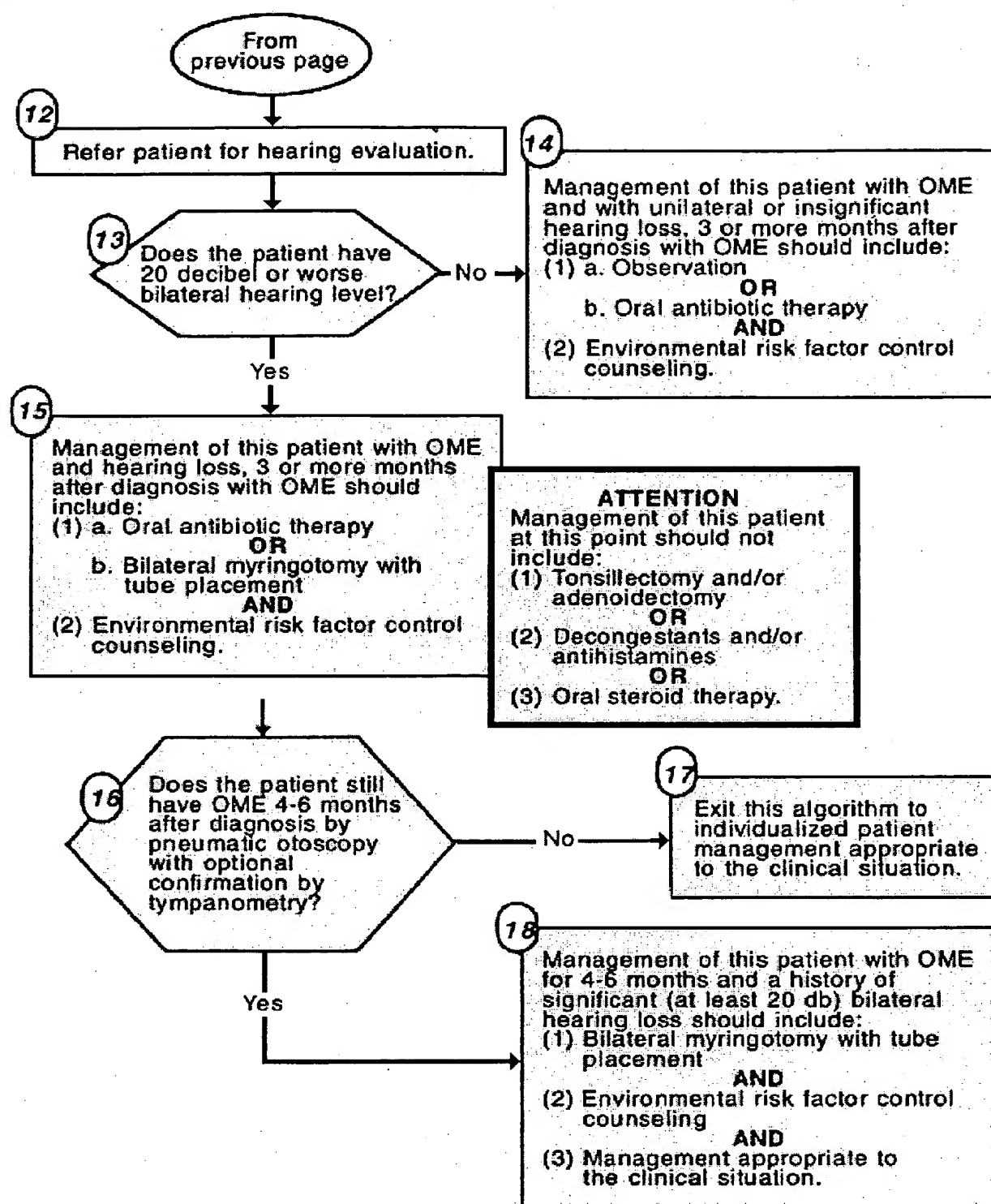


TABLE. Outcomes of Treating Otitis Media With Effusion*

Intervention	Benefits†	Harms‡
Observation	Base case	Base case
Antibiotics	Improved clearance of effusion at 1 month or less, 14.0% (95% CI [3.6%, 24.2%]); possible	Nausea, vomiting, diarrhea (2% to 32% depending on dose and antibiotic); cutaneous reactions (<= 5%);
	reduction in future infections	numerous rare organ system effects, including very
		rare fatalities; cost; possible development of resistant
		strains of bacteria
Antibiotics plus steroids	Possible improved clearance at 1 month, 25.1%	See antibiotics and steroids separately
	(95% CI [-1.3%, 49.9%]) §; possible reduction	
	in future infections.	
Steroids alone	Possible improved clearance at 1 month, 4.5%	Possible exacerbation of varicella; long-term
	(95% CI [-11.7%, 20.6%]) §	complications not established for low doses; cost
Antihistamine/decongestant	Same as base case	Drowsiness and/or excitability¶; cost
Myringotomy with tubes	Immediate clearance of effusion in all children;	Invasive procedure; anesthesia risk; cost;
	improved hearing	tympanosclerosis; otorrhea; possible restrictions on
		swimming
Adenoidectomy	Benefits for young children have not been	Invasive procedure¶; anesthesia risk; cost
	established	
Tonsillectomy	Same as base case	Invasive procedure¶; anesthesia risk; cost

* The target patient is an otherwise healthy child age 1 through 3 years with no craniofacial or neurologic abnormalities or sensory deficits.

† Outcomes are reported as differences from observation, which is treated as the base case. When possible, meta-analysis was performed to provide a mean and associated confidence interval (CI).

§ Difference from base case not statistically significant.

¶ Risks were not examined in detail because no benefits were identified.

TREATMENT OF OTITIS MEDIA: AN UPDATE, REVISIONS AND RECONSIDERATION OF ESTABLISHED GUIDELINES

by Dr. Moshe Ipp

What has brought about the latest recommendations in terms of modifying the treatment for otitis media?

The increasing worldwide prevalence of infection due to multiple-drug-resistant organisms has become the biggest threat to mankind and the most formidable challenge facing the medical profession as we enter the 21st Century. The use of antibiotics, particularly for otitis media remain an important contributor to the development of *Streptococcus Pneumoniae* drug resistance. A modified approach to the use of antibiotics for otitis media must be considered in this light.

What is different about S. Pneumoniae resistance?

Unlike resistance to amoxicillin by certain strains of *Haemophilus Influenzae* and most strains of *Moraxella catarrhalis*- which is mediated via beta-lactamases (and can therefore be largely obviated by using a drug which is resistant to beta-lactamase activity), resistance to the penicillins by various strains of *S. pneumoniae* is mediated by an entirely different mechanism: alteration in penicillin binding proteins. This type of resistance is therefore not affected by measures aimed at blocking or resisting beta-lactamase activity.

Why is S. Pneumoniae resistance so important in otitis media?

S. Pneumoniae is the most common organism causing otitis media in children.

Are any children at greater risk for developing pneumococcal resistance?

The prevalence of resistant pneumococcal strains is higher in children who have recently been treated with beta-lactam drugs and those who attend day care centers. Both the development of resistant strains and their rapid spread have likely been fostered and facilitated by selective pressures resulting from extensive use of antibiotics.

What strategies should now be considered in treating otitis media?

1. The duration of antibiotic treatment should be individualized according to each patient.
2. Antibiotic treatment for serous otitis media (otitis media with effusion, OME) is not necessary and should be eliminated except for specific indications (See below).
3. Antibiotic prophylaxis for the prevention of recurrent acute otitis media should be reconsidered.

For how long should acute otitis media (AOM) be treated?

AOM is defined as a middle ear effusion, usually purulent, occurring in a child with recent ear pain, marked redness of the ear drum and bulging of the tympanic membrane. An empirical course of 10 days of antibiotic is usually prescribed but in certain situations a 5 day course may be sufficient e.g. the older child with a mild episode, occurring in the summer months and who has little or no previous history of

otitis media.

How should serous otitis media (OME) be treated?

OME may occur either from following an episode of AOM or as a result of eustachian tube obstruction following an upper respiratory tract infection. Most episodes of OME resolve spontaneously in 1 to 3 months and require no antibiotic treatment. Antibiotics should be used if:

- (1) acute ear pain develops in association with the effusion.
- (2) the serous effusion changes to a purulent effusion.
- (3) the effusion persists for more than 3 months with an associated conductive hearing loss of greater than 30 decibels. Antibiotics should be given in this situation before resorting to tube placement.

What recommendations are advised for managing recurrent AOM?

(More than 3 episodes in 6 months or 4 episodes within 1 year).

Although there is evidence to show that continuous antibiotic prophylaxis provides variable protection against the development of recurrent AOM, its risks particularly with regard to the development of pneumococcal resistance likely outweigh its benefits. Current revised recommendations therefore include:

- (1) the use of intermittent prophylactic antibiotics beginning at the first sign of an upper respiratory tract infection (URI) and discontinued after the URI has resolved.
- (2) the placement of tubes
- (3) for older children with recurrent AOM who have undergone one or more tube placements, adenoidectomy may be efficacious in reducing the risk of subsequent occurrences of AOM.

What does the future hold in store for the management of otitis media?


Research is currently in the works for the development of a vaccine against the common organisms which cause otitis media. Meanwhile the influenza vaccine may provide limited protection against AOM in some children, particularly in day care centers. The use of polyvalent pneumococcal vaccine in children older than 2 years of age may protect against pneumococcal specific episodes, without reducing the overall occurrence of AOM.

Parental input?

Physicians should discuss the relative benefits and risks of the various treatment options with the child's parents, so that they can participate as knowledgeably as possible in the decision making process. Some parents will express a clear desire for surgical intervention and tube placement and some will alternately avoid such treatment at all costs.

PEARLS

1. *S. Pneumoniae* is the most common bacterial organism causing otitis media in children.
2. The increasing prevalence of *S. Pneumoniae* resistance is alarming.
3. Shorter courses of antibiotic treatment for otitis media should be considered in selected children.
4. Antibiotics should be avoided in children with serous otitis media.
5. Antibiotic prophylaxis for recurrent acute otitis media should be reconsidered.

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